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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,112	01/11/2001	Sybillie Muller	200-013	1831

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JAMES H. MEADOWS AND MEDICUS ASSOCIATES
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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/759,112

Applicant(s)

MULLER ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2001.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 2, 6-8, and 12-15 drawn to polynucleotides encoding a CDR of an anti-idiotypic antibody that binds human or primate anti-HIV antibodies, classified in class 536, subclass 23.53.
 - II. Claims 1-5, and 12-15, drawn to polynucleotides encoding a FR of an anti-idiotypic antibody that binds human or primate anti-HIV antibodies, classified in class 536, subclass 23.53.
 - III. Claims 1, 2, 9, 10, 11, and 12-15, drawn to polynucleotides encoding all of the CDRs or FRs of an anti-idiotypic antibody that binds human or primate anti-HIV antibodies, classified in class 536, subclass 23.53.
 - IV. Claims 1, 16, and 17, drawn to polypeptides encoded by a polynucleotide encoding a CDR of an anti-idiotypic antibody that binds human or primate anti-HIV antibodies, classified in class 530, subclass 387.2.
 - V. Claims 1, 16, and 17, drawn to polypeptides encoded by a polynucleotide encoding a FR of an anti-idiotypic antibody that binds human or primate anti-HIV antibodies, classified in class 530, subclass 387.2.
 - VI. Claims 1, 16, and 17, drawn to polypeptides encoded by a polynucleotide encoding all of the CDRs and FRs of an anti-idiotypic antibody that binds human or primate anti-HIV antibodies, classified in class 530, subclass 387.2.

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- VII. Claims 19 and 20, drawn to methods of modulating the immune response of a host infected with HIV, by administering a polynucleotide encoding a CDR, a FR, or all of the CDRs and FRs, of an anti-idiotypic antibody that binds human or primate anti-HIV antibodies, classified in class 514, subclass 44.
- VIII. Claim 18, drawn to methods of modulating the immune response of a host infected with HIV, by administering a polypeptide encoded by a polynucleotide encoding a CDR, a FR, or all of the CDRs and FRs, of an anti-idiotypic antibody that binds human or primate anti-HIV antibodies, classified in class 514, subclass 2.

For Groups I and IV above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VIII, and, if one of Groups I or IV is elected, then election is also required to one of inventions I/IV (A)- I/IV (F). The inventions of subgroups I/IV I (A)- (F) represent the elected Group of inventions wherein the polypeptide or polynucleotide has, or encodes:

- I/IV (A) the polypeptide of SEQ ID NO: 11, or the DNA sequence of SEQ ID NO: 10;
- I/IV (B) the polypeptide of SEQ ID NO: 15, or the DNA sequence of SEQ ID NO: 14;
- I/IV (C) the polypeptide of SEQ ID NO: 19, or the DNA sequence of SEQ ID NO: 18;
- I/IV (D) the polypeptide of SEQ ID NO: 28, or the DNA sequence of SEQ ID NO: 27;
- I/IV (E) the polypeptide of SEQ ID NO: 32, or the DNA sequence of SEQ ID NO: 31; or
- I/IV (F) the polypeptide of SEQ ID NO: 36, or the DNA sequence of SEQ ID NO: 35.

For Groups II and V above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VIII, and, if one of Groups II or V is

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elected, then election is also required to one of inventions II/V (A)-II/V (H). The inventions of subgroups II/V (A)- (H) represent the elected Group of inventions wherein the polypeptide or polynucleotide has, or encodes:

- II/V (A) the polypeptide of SEQ ID NO: 9, or the DNA sequence of SEQ ID NO: 8;
- II/V (B) the polypeptide of SEQ ID NO: 13, or the DNA sequence of SEQ ID NO: 12;
- II/V (C) the polypeptide of SEQ ID NO: 17, or the DNA sequence of SEQ ID NO: 16;
- II/V (D) the polypeptide of SEQ ID NO: 21, or the DNA sequence of SEQ ID NO: 20;
- II/V (E) the polypeptide of SEQ ID NO: 26, or the DNA sequence of SEQ ID NO: 25;
- II/V (F) the polypeptide of SEQ ID NO: 30, or the DNA sequence of SEQ ID NO: 29;
- II/V (G) the polypeptide of SEQ ID NO: 34, or the DNA sequence of SEQ ID NO: 33; or
- II/V (H) the polypeptide of SEQ ID NO: 38, or the DNA sequence of SEQ ID NO: 37.

For Groups III and VI above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VIII, and, if one of Groups III or VI is elected, then election is also required to one of inventions III/VI (A) or III/VI (B). The inventions of subgroups III/VI (A) and (B) represent the elected Group of inventions wherein the polypeptide or polynucleotide has, or encodes:

- III/VI (A) the polypeptide of SEQ ID NO: 7, or the DNA sequence of SEQ ID NO: 5; or
- III/VI (B) the polypeptide of SEQ ID NO: 24, or the DNA sequence of SEQ ID NO: 22.

For Groups VII and VIII above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VIII, and, if one of Groups VII or VIII is elected, then election is also required to one of inventions VII/VIII (A) - VII/VIII (P). The

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inventions of subgroups VII/VIII (A)-(P) represent the elected Group of inventions wherein the polypeptide or polynucleotide has, or encodes:

VII/VIII (A) the polypeptide of SEQ ID NO: 11, or the DNA sequence of SEQ ID NO: 10;
VII/VIII (B) the polypeptide of SEQ ID NO: 15, or the DNA sequence of SEQ ID NO: 14;
VII/VIII (C) the polypeptide of SEQ ID NO: 19, or the DNA sequence of SEQ ID NO: 18;
VII/VIII (D) the polypeptide of SEQ ID NO: 28, or the DNA sequence of SEQ ID NO: 27;
VII/VIII (E) the polypeptide of SEQ ID NO: 32, or the DNA sequence of SEQ ID NO: 31;
VII/VIII (F) the polypeptide of SEQ ID NO: 36, or the DNA sequence of SEQ ID NO: 35;
VII/VIII (G)) the polypeptide of SEQ ID NO: 9, or the DNA sequence of SEQ ID NO: 8;
VII/VIII (H) the polypeptide of SEQ ID NO: 13, or the DNA sequence of SEQ ID NO: 12;
VII/VIII (I) the polypeptide of SEQ ID NO: 17, or the DNA sequence of SEQ ID NO: 16;
VII/VIII (J) the polypeptide of SEQ ID NO: 21, or the DNA sequence of SEQ ID NO: 20;
VII/VIII (K) the polypeptide of SEQ ID NO: 26, or the DNA sequence of SEQ ID NO: 25;
VII/VIII (L) the polypeptide of SEQ ID NO: 30, or the DNA sequence of SEQ ID NO: 29;
VII/VIII (M) the polypeptide of SEQ ID NO: 34, or the DNA sequence of SEQ ID NO: 33;
VII/VIII (N) the polypeptide of SEQ ID NO: 38, or the DNA sequence of SEQ ID NO: 37;
VII/VIII (O) the polypeptide of SEQ ID NO: 7, or the DNA sequence of SEQ ID NO: 5; or
VII/VIII (P) the polypeptide of SEQ ID NO: 24, or the DNA sequence of SEQ ID NO: 22.

The inventions are distinct, each from the others, for the following reasons:

2. The inventions of Groups I/IV I (A)- (F), Groups II/V (A)- (H), Groups III/VI (A) and (B), and Groups VII/VIII (A)-(P) are each related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. See MPEP § 806.05(d). In the instant case, each of the inventions has the same separate utility as the other subcombinations in its respective Group (I-VIII).

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The inventions of Groups I and IV, and of Groups II and V are related as subcombinations usable together.). In the instant case, each of the inventions has the same separate utility as the other subcombinations.

3. The inventions of Groups I, III, and VII, and of Groups II, IV, and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions Each of Groups I, III, and VII relate to a different type of molecule (polynucleotides) from those of Groups II, IV, and VIII (polypeptides). Because these different molecules have different structures, and perform different functions, they are not related.

4. The inventions of Groups III and IV are related, respectively, as combination and subcombinations with the inventions of Groups I and II, or Groups IV and V. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combinations as claimed do not require the particulars of any subcombination as claimed because the combinations may rely on any one of the subcombinations, or on the combination of the combinations for patentability. The subcombinations each have the same separate utility as the combinations.

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5. The inventions of Groups I-VI are related as product and process of use with the inventions of Groups VII and VIII. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, each of the processes of Groups VII and VIII may be performed with any of the various products in two or more of Groups I-VI.

Conclusion

6. Because these inventions are distinct for the reasons given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

7. It is here noted that some of the restrictions requirements made above fall within the scope of PTO Linking claim practice. In accordance with this practice as described in MPEP 809.03, linking claims will be considered with the elected invention. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn.

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8. Applicant's attention is hereby directed to the following is a recitation of M.P.E.P.

§821.04 regarding the restriction of claims to a product and processes of using the product,

Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. Amendments submitted after final rejection are governed by 37 CFR 1.116. Process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments submitted after allowance are governed by 37 CFR 1.312. Process claims which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of an allowed product claim**. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

In accordance with M.P.E.P. §821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy,

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Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

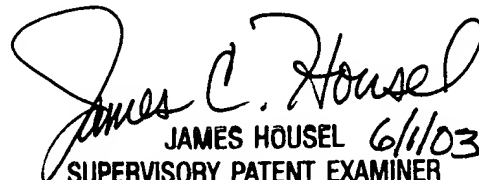
9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Z. Lucas
Patent Examiner
May 29, 2003


JAMES HOUSEL 6/1/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600